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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/515,283	02/29/2000	Nora Aghassi	P-6335.01CIP	1899

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EXAMINER	
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ART UNIT	PAPER NUMBER
1641	14

DATE MAILED: 01/29/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/515,283	AGHASSI et al.
Examiner	**Art Unit**
James L. Grun, Ph.D.	1641

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *19 Nov 2001 and 30 Nov 2001*.

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *17-44* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *17-44* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☒ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
18) ☐ Interview Summary (PTO-413) Paper No(s). _____
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other:

To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Technology Center 1600, Group 1640, Art Unit 1641.

The Request for a Continued Prosecution Application under 37 CFR § 1.53(d), apparently filed 19 October 2001 and received by the USPTO on 19 November 2001 by OIPE and 10 January 2002 by Technology Center 1600, is acknowledged. It is noted that the paper apparently deposited with the U.S. Postal Service on 19 October 2001 could not be taken as a duplicate of the papers filed 01 October 2001. Applicant's representative should carefully check the Attorney Docket Nos. (P-6335.01CIP vs. P-6335.01CPA, respectively) on these two submissions to perhaps prevent future submission problems. The amendment filed 30 November 2001 is acknowledged and has been entered. Claims 17-44 are newly added by the amendment filed 30 November 2001. Claims 1-16 have been cancelled. Claims 17-44 remain in the case.

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). It is noted that the addition directed to page 8 of the specification, at the end of the first paragraph, in the amendment filed 30 November 2001 could not be entered because it was not in the proper form for entry and appears to be mis-directed. Correction of the following is required: the limitations from original claim 9 should be entered into the specification by the appropriate replacement of the paragraph in which it is being entered, perhaps adding the limitations at the end of the paragraph bridging pages 8-9.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:

> It does not state that the person making the oath or declaration in a continuation-in-part application filed under the conditions specified in 35 U.S.C. 120 which discloses and claims subject matter in addition to that disclosed in the prior copending application, acknowledges the duty to disclose to the Office all information known to the person to be material to patentability as defined in 37 CFR 1.56 which occurred between the filing date of the prior application and the national or PCT international filing date of the continuation-in-part application.

Claims 17-44 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 17-44, recitations of percent surfactant are not clear because it is not clear on what basis the percentage is determined, i.e. it is not clear if a weight or volume percentage is intended, and one would not know what surfactant concentrations were encompassed. The claimed subject matter would also be clearer if --at least one tissue activating agent selected from a buffer, salt, or chelator-- was recited.

In claims 20 and 34, the claimed subject matter would be clearer if --at least one of a cationic, anionic, amphoteric, or nonionic surfactant-- was recited.

In claims 24, 25, 36, 38, 39, and 42, improper Markush language is used to claim the members of the group. The alternatives "is at least one of...or", or "selected from...or", or "selected from the group consisting of...and" are acceptable.

Claim 30 does not provide any further limitation of the composition of claim 17 itself, rather the claim attempts to limit the intended use of the composition.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 17-21, 23, 27-35, 37, and 41-44 are rejected under 35 U.S.C. § 102(b) as being anticipated by Cell Marque Corporation ("Immuno Pathology 1998 Products & Reference Guide") in light of the instant disclosure and Kennedy (U.S. Patent No. 5,856,289).

Cell Marque Corporation discloses the DECLERE™ epitope unmasking solution, offers the solution for sale (e.g. page 45), and teaches how to use the solution for epitope unmasking in a single step with heating (e.g. page 2). In light of the instant disclosure at pages 13-15 and 24, that the DECLERE™ epitope unmasking solution is the SIMPLE GREEN formulation of

Example 1, and the current composition of SIMPLE GREEN taught in Kennedy, the reference inherently teaches the composition and method as instantly claimed.

Note that the instant claims have not been accorded the benefit of the filing date of the parent application, USSN 08/957,098, because the parent application does not provide written description support or enablement for the invention of the scope as instantly claimed.

Claims 17-44 are rejected under 35 U.S.C. § 103(a) as being unpatentable over the combined teachings of Hazelbag et al (J. Histochem. Cytochem. 43: 429-437, 1995), Shi et al (J. Histochem. Cytochem. 43: 193-201, 1995), and Yörükoğlu et al (Appl. Immunohistochem. 5: 71, 1997) for reasons of record in the prior rejection of the similar subject matter of claims 1, 3, 5, 6, 8-10, and 12-16.

Claims 17-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hazelbag et al, Shi et al, and Yörükoğlu et al, and, if necessary, further in view of either of Norton et al (J. Pathol. 173: 371-9, 1994) or Miller et al (Applied Immunohistochem. 3: 190-3, 1995) for reasons of record in the prior rejection of the similar subject matter of claims 1, 3, 5, 6, 8-10, and 12-16.

Applicant's arguments filed 30 November 2001 have been fully considered but they are not deemed to be persuasive.

In response to Applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re*

Merck & Co., 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Notwithstanding applicant's assertions to the contrary, the reference of Hazelbag et al clearly teaches the use of a heated detergent for antigen retrieval. Applicant has previously urged that the references do not teach a single step process. This is not found persuasive for reasons of record, particularly in view of the teachings of Yörükoğlu et al.

In response to applicant's previous argument that the prior art does not teach detergent in the composition as emulsifier, or as a "removing agent" as is now claimed, the fact that Applicant has recognized another advantage which would flow naturally from following the suggestions of the combined prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James L. Grun, Ph.D., whose telephone number is (703) 308-3980. The examiner can normally be reached on weekdays from 9 a.m. to 5 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le, SPE, can be contacted at (703) 305-3399.

The phone numbers for official facsimile transmitted communications to TC 1600, Group 1640, are (703) 872-9306, or (703) 305-3014, or (703) 308-4242. Official After Final communications, only, can be facsimile transmitted to (703) 872-9307.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196. The above inquiries, or requests to supply missing elements from Office communications, can also be directed to the TC 1600 Customer Service Office at phone numbers (703) 308-0197 or (703) 308-0198.

James L. Grun, Ph.D.
January 25, 2002

CHRISTOPHER L. CHIN
PRIMARY EXAMINER
GROUP 1800/1641